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Joint Program Executive Office for Chemical and Biological Defense Medical Virtual Industry Day

Joint Program Executive Office for Chemical and Biological Defense

Improved Nerve Agent Treatment System (INATS)

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Disclaimer

- **While we are presenting our currently planned Business Opportunities, we recognize that these may change given our changing fiscal environment and the strategic guidance of the Department of the Defense.**
- **New starts and increases to production levels in FY13 will be delayed until the Appropriations Bill is passed.**

Capability Gap & Product Description

Capability Gap:

- Fielded nerve agent antidotes do not adequately protect the operational force against traditional nerve agents and NTAs
- Pyridostigmine Bromide (PB) is FDA approved as a pretreatment for only soman
- Pralidoxime (2-PAM), FDA-approved for the treatment of nerve agent intoxication, may not provide adequate treatment against all traditional and non-traditional agents

Product Description:

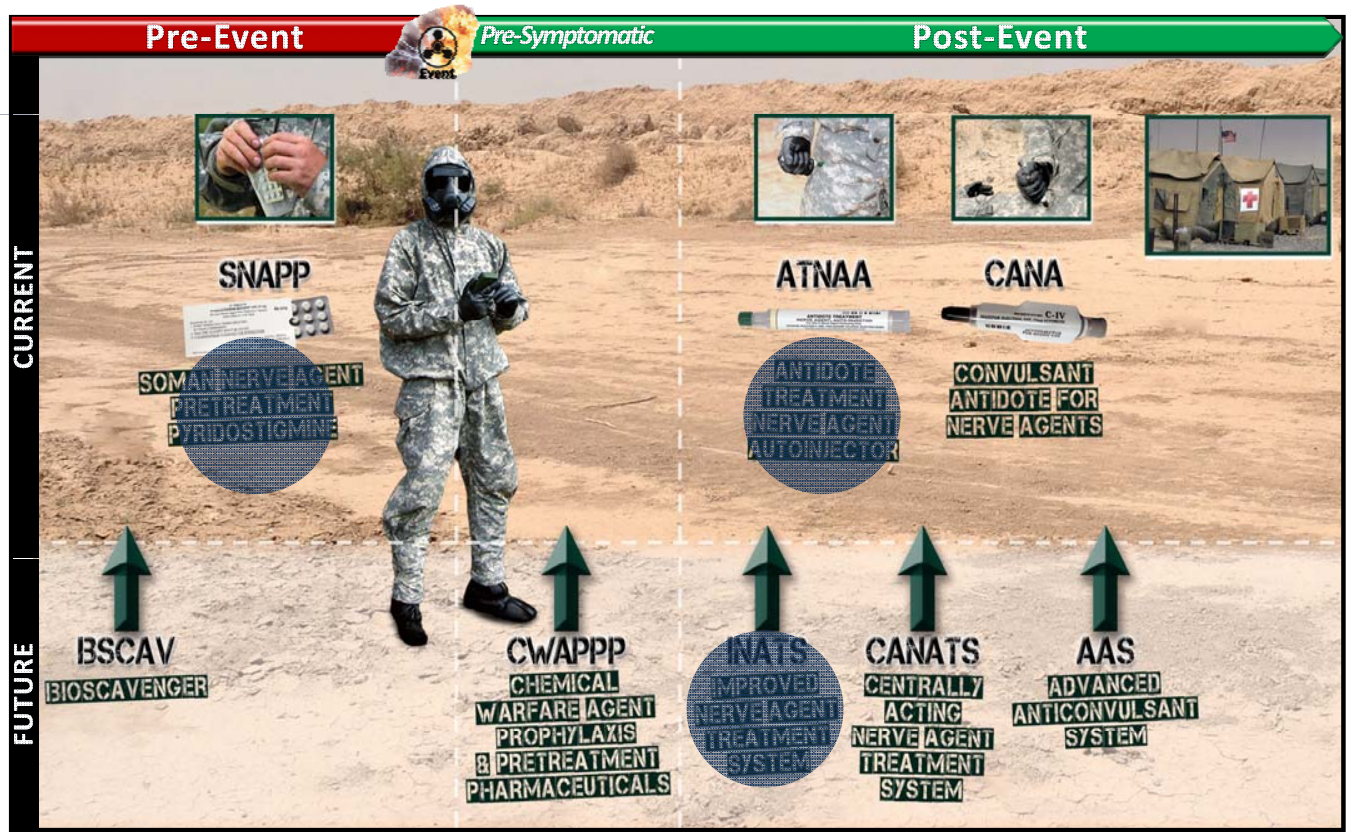
An enhanced treatment regimen consisting of broad spectrum oxime to replace the fielded oxime 2-PAM and expanded pretreatment indications for PB

This is a replacement product to the currently fielded Antidote Treatment – Nerve Agent-Autoinjector (ATNAA), atropine and 2-PAM

Temperature stable formulation that offers increased chemical stability and shelf-life

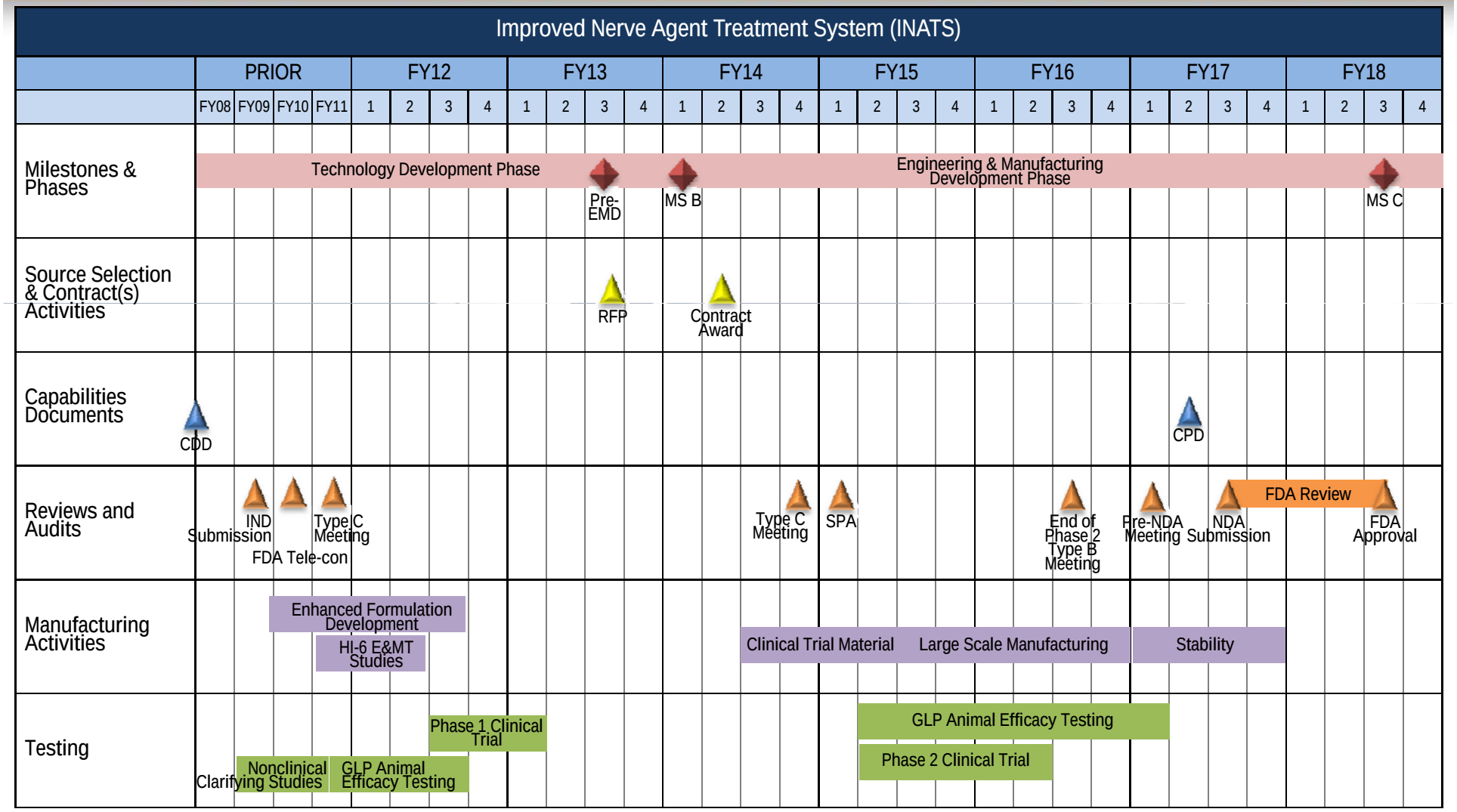
Product Fit in the Family of Systems

- **INATS is a broad spectrum therapeutic that works in conjunction with pre- and post-medical countermeasures to provide increased survival, against traditional and non-traditional agents**



** With typical dose & against various agents of interest*

Product Schedule



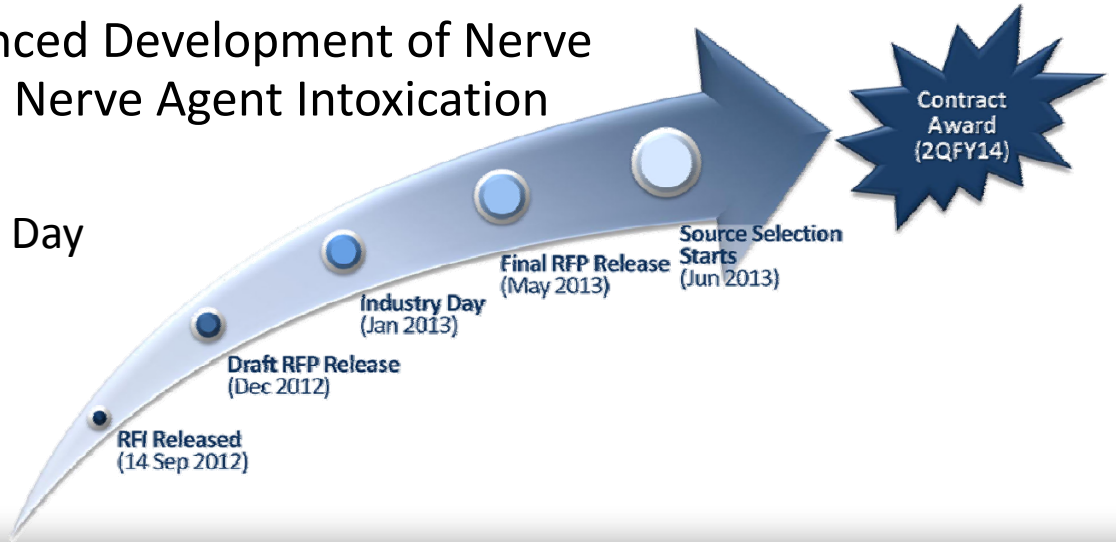
Acquisition and Contracting Strategy

Acquisition Strategy:

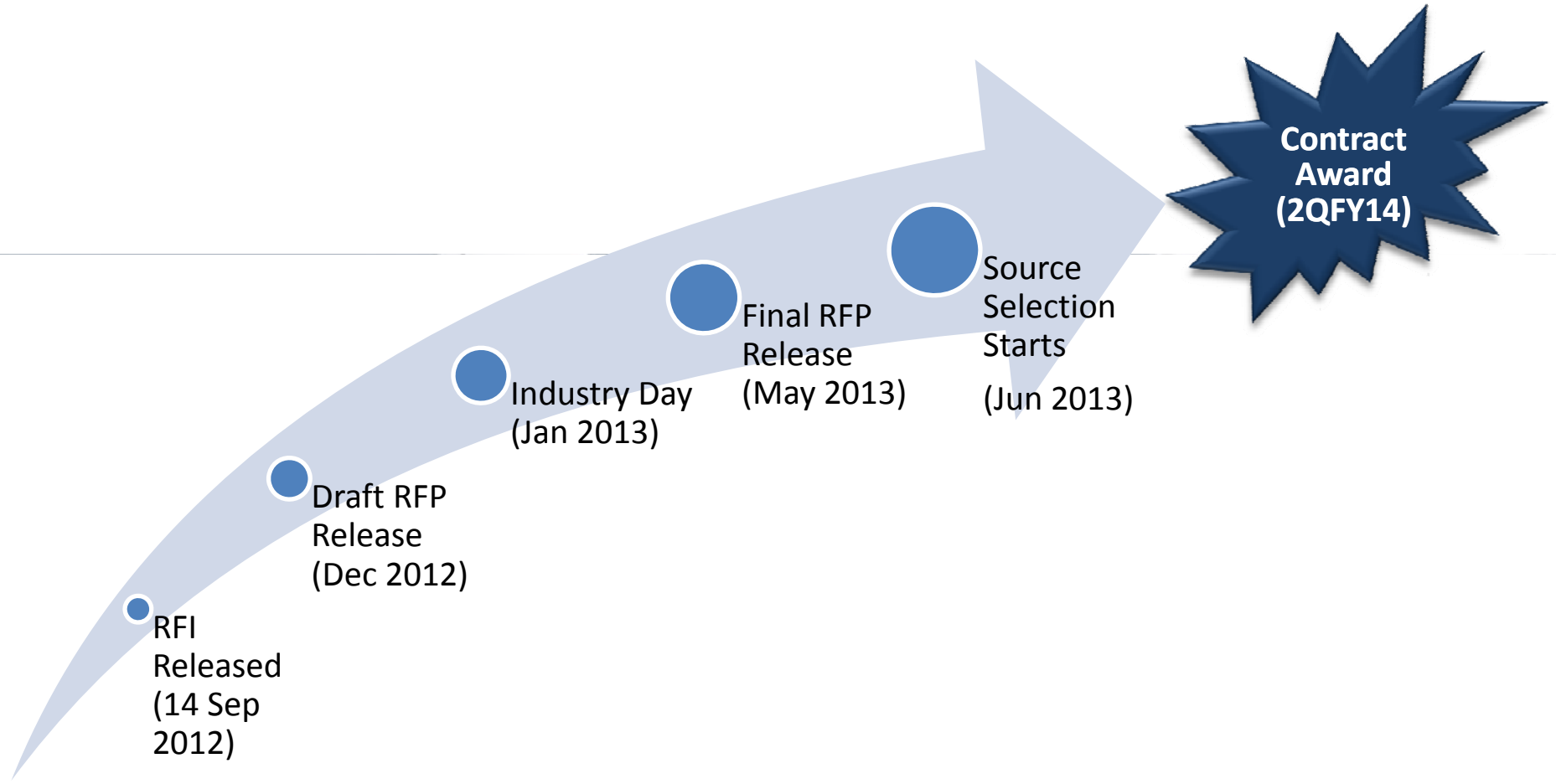
CBMS-MITS will partner with commercial entities during the Engineering and Manufacturing Phase (EMD) Phase to ensure the development and manufacture of the INATS in accordance with FDA guidelines

Contracting Strategy:

- 14 Sep 2012: Released Request for Information (W911QY-12-S-0022) – Advanced Development of Nerve Agent Therapeutic(s) to Treat Nerve Agent Intoxication
- Industry Days
  - 15 Nov 2012: Virtual Industry Day
  - Feb 2013: INATS Industry Day
- Request for Proposal (RFP)
  - Dec 2012: Release Draft RFP
  - May 2013: Release Final RFP



Contracting Strategy



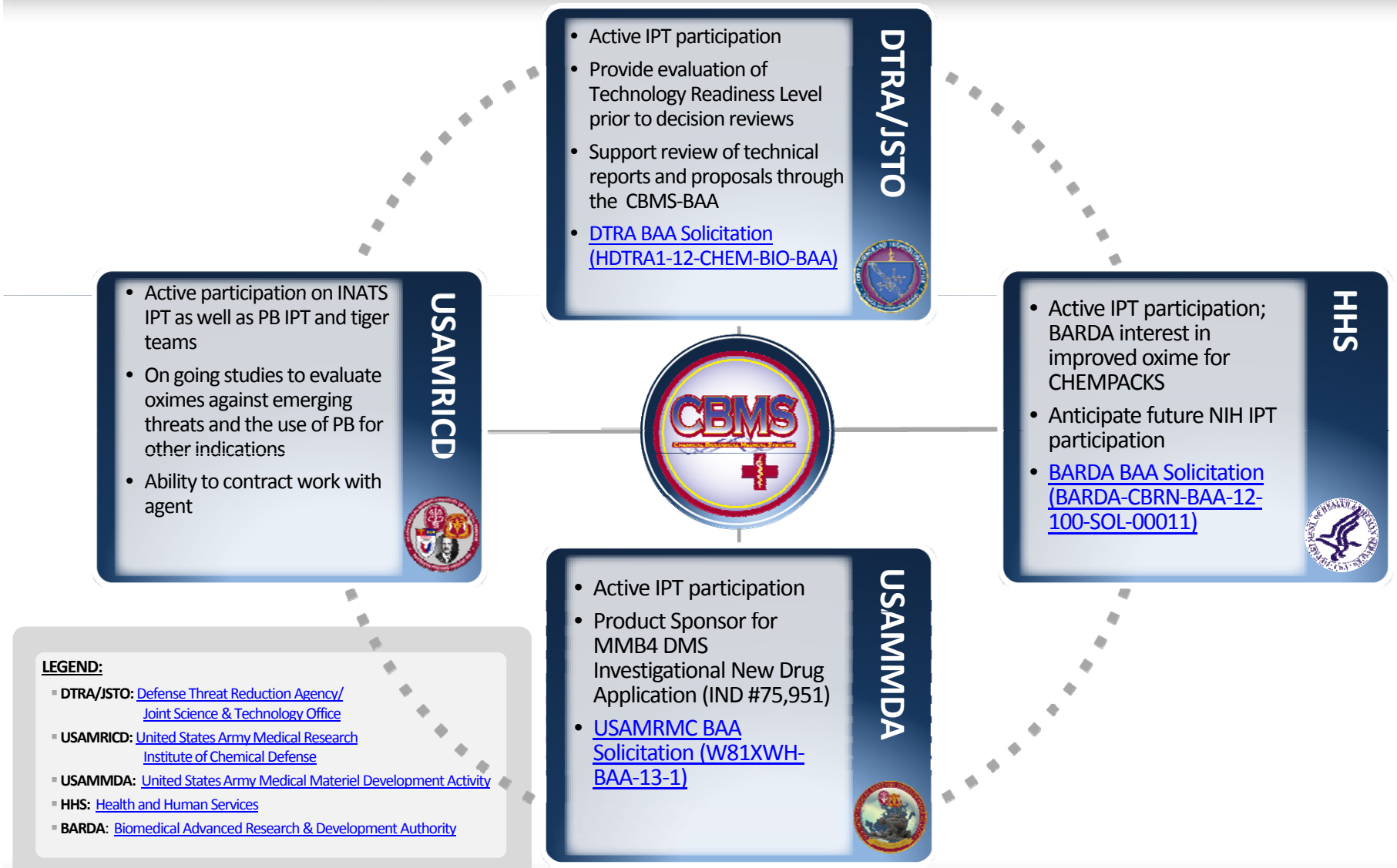
Technology Gap

Current	Business Motivation	Future
Traditional Agents	Provide Warfigher ***FDA approved*** post-symptomatic treatment for the adverse medical effects of nerve agents and NTAs	Emerging Threats
PB Pretreatment - Protection Against Soman	Provide Warfighter ***FDA approved*** pretreatments to provide comprehensive protection against adverse effects of exposure to nerve agents and NTAs	PB Pretreatment- Expanded Indications
Dual-Chambered Autoinjector Aqueous Formulations	Provide Warfighter with reduced number of injections and logistics burden associated with carrying multiple autoinjectors	Single Chamber Autoinjector Nonaqueous Formulations

Business Opportunities

- **Anticipate 2QFY14 contract award**
  - Phase 2 human clinical safety study
  - Toxicology and definitive animal efficacy studies
  - Manufacturer of improved oxime and delivery system
  - Studies to support expanded pretreatment indications for PB
- **As funding permits, explore opportunities for dual prototyping and improvements to the existing nerve agent treatment regimen through task order vehicles and CBMS BAA (CBMS-BAA-07-01)**
  - Studies to refine the MMB4 enhanced formulation
  - Studies to evaluate candidate oximes in support of oxime risk mitigation strategy with international partners
  - Studies to investigate auto-injector refinements

Collaboration Partnerships



Points of Contact

Learn how we partner with industry, other government agencies and academia.
www.jpeocbd.osd.mil/packs/Default.aspx?pg=1207

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Acronym Glossary

ADM: Acquisition Decision Memorandum or Advanced Development & Manufacturing
AoA: Analysis of Alternatives
APUC: Acquisition Procurement Unit Cost
AS: Acquisition Strategy
BARDA: Biomedical Advanced Research and Development Authority
BBP: Better Buying Power
BLA: Biologics License Application
BSV: Biosurveillance
CBMS: Chemical Biological Medical Systems
CDD: Capability Development Document
CPD: Capability Production Document
cGMP: Current Good Manufacturing Practice
CONOPS: Concept of Operations
CPIF: Cost Plus Incentive Fee
DARPA: Defense Advanced Research Projects Agency
DHS: Department of Homeland Security
DoD: Department of Defense
DSTL: Defense Science Technology Laboratory
DTRA/JSTO: Defense Threat Reduction Agency/Joint Science and Technology Office
EMD: Engineering Manufacturing and Development
EPA: Environmental Protection Agency
FDA: US Food & Drug Administration
FFP: Fixed Firm Price
FOC: Full Operational Capability
FRP: Full Rate Production
FY: Fiscal Year
HHS: Health and Human Services
IBR: Integrated Baseline Review
ICD: Initial Capabilities Document
IND: Investigational New Drug
IOC: Initial Operational Capability
JILA: Joint Integrated Logistics Assessment
JPEO: Joint Program Executive Office(r)
JPM: Joint Project/Product Manager
JPM-ADM: Joint Project Manager- Advanced Development & Manufacturing
JPMO: Joint Project/Product Management Office
JRO-CBRND: Joint Requirements Office for Chemical, Biological, Radiological, and Nuclear Defense
JVAP: Joint Vaccine Acquisition Program
KPP: Key Performance Parameter
KSA: Key System Attribute
LCCE: Life Cycle Cost Estimate
LCMP: Life Cycle Management Plan
LCSP: Life Cycle Sustainment Plan
LRIP: Low Rate Initial Production
MDA: Milestone Decision Authority
MITS: Medical Identification and Treatment Systems
MS: Milestone
MSR: Manufacturing Sustainment Rate
NDA: New Drug Application
NGDS: Next Generation Diagnostic System
NIH: National Institutes of Health
NTA: Non-Traditional Agent
O&M: Operation and Maintenance
OASD (HA): Office of the Assistant Secretary of Defense (Health Affairs)
OGA: Other Government Agency
OSD (NCB/CB): Office of the Secretary of Defense (Nuclear/Chemical Biological)
OSTP: Office of Science and Technology Policy
OUSD(C): Office of the Under Secretary of Defense (Comptroller)
PAIO: Joint CBRN Defense Program Analysis Integration Office
RDT&E: Research, Development, Test and Evaluation
RFP: Request For Proposal
SEP: Systems Engineering Plan
SNS: Strategic National Stockpile
SPA: Special Protocol Assessment
TD: Technology Development
TDP: Technical Data Package
TED: Troop Equivalent Dose
THP: Trained Health Care Provider
TMT: Transformational Medical Technologies
TOA: Total Obligation Authority
TRA: Technology Readiness Assessment
TRL: Technology Readiness Level
USAMMDA: US Army Medical Materiel Development Activity
USAMRIID: US Army Medical Research Institute of Infectious Disease
USAMRICD: US Army Medical Research Institute of Chemical Defense
USAMRMC: US Army Medical Research and Materiel Command